

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

Maryland Board of Pharmacy Deena Speights-Napata, M.A Executive Director 4201 Patterson Avenue Baltimore, MD 21215

July 14, 2020

BY REGULAR & CERTIFIED MAIL RETURN RECEIPT REQUESTED ARTICLE #7018 1130 0002 2824 7107

Walgreen's Pharmacy # 5408 1300 E. North Avenue Baltimore, Maryland 21213

Attn: Daniel Won Lee, R.Ph., Pharmacy Manager

Re:

Permit No. P06742 Case No. 20-377

Notice of Deficiencies, Recommended Civil Monetary Penalty, and

Opportunity for Hearing

# Dear Pharmacy Manager:

On April 15, 2020, the Board of Pharmacy (the "Board") reviewed the results of an annual inspection conducted on February 25, 2020 of Walgreen's Pharmacy #5408 (the "Pharmacy") for compliance with statutes and regulations governing the operation of a pharmacy. The Board's inspection indicated that the Pharmacy was not compliant with laws relating to labeling and storage of prescription drugs. Specifically, the Board inspector noted a prepared prescription for Lantus Solostar Pen Inj. 3 ml in the medication refrigerator with a label stating "use before mfg. labeled date" instead of an expiration date 1 year from the date of dispensing. In addition, the inspector noted five expired medications in the prescription drug area and 3 expired OTC medications during a spot check of the Pharmacy's inventory. Both issues were noted on the Pharmacy's previous inspection on July 25, 2019.

### I. FINDINGS AND CONCLUSION

The Board finds that the Pharmacy prepared for dispensing a medication labeled with an incorrect expiration date, referring generally to the manufacturer's expiration date rather than 1 year from the date of dispensing. The Board also finds that the Pharmacy had approximately five

outdated medications in the prescription area and three outdated OTC medications. Both deficiencies are noted in the Board's Inspection Report dated July 25, 2019.

Based upon deficiencies at your Pharmacy, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act. Specifically, the Board finds the Pharmacy in violation of Health Occ. Art. §§ 12-403(c)(12), (16) and 12-505 and COMAR 10.34.12.

## II. RECOMMENDED CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-410 and COMAR 10.34.11, the Board of Pharmacy has the authority to impose a civil monetary penalty based upon violations of the Maryland Pharmacy Act.

Based upon the deficiencies cited at the Pharmacy, the Board hereby recommends the imposition of a **civil monetary penalty of \$2,500.00**. The deficiencies upon which the civil monetary penalty is based are set forth in the Notice above and in the Inspection Report dated February 25, 2020.

In determining the recommended civil monetary penalty, the Board took into consideration the aggregating and mitigating factors outlined in COMAR 10.34.11.08.

#### III. FOLLOW-UP INSPECTION

Please be advised that the Board of Pharmacy may perform a follow-up inspection of the Pharmacy to ensure that the deficiencies noted herein have been addressed and corrected. Should the follow-up inspection indicate further or continued deficiencies, the Board may pursue further disciplinary action against the Pharmacy that may result in the imposition of sanctions such as suspension, revocation or additional monetary penalties.

## IV. OPPORTUNITY FOR HEARING

If the Pharmacy disputes the findings, conclusions or the civil monetary penalty, the Pharmacy may request an evidentiary hearing on the Board's decision in this matter. In the event that the Pharmacy requests an evidentiary hearing, the Board shall initiate formal proceedings which will include the opportunity for a full evidentiary hearing. The hearing will be held in accordance with the Administrative Procedure Act, Md. Code Ann. State Gov't § 10-201 et seq., and COMAR 10.34.01. Any request for a hearing must be submitted in writing to Donna

Goldberg, R.Ph., J.D., Maryland Board of Pharmacy, 4201 Patterson Ave., 5th Floor, Baltimore, Maryland 21215, no later than thirty (30) days from the date of this Notice.

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cc:

Please be advised that at the hearing the Pharmacy would have the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on its own behalf, to present evidence, to cross-examine witnesses, to testify, and to present summation and argument. Should the Board find the Pharmacy guilty of the violations cited in the Report, the Board may suspend or revoke the pharmacy permit, impose civil penalties, or both. If the Pharmacy requests a hearing but fails to appear, the Board may nevertheless hear and determine the matter in its absence.

# V. OPTION TO PAY RECOMMENDED CIVIL MONETARY PENALTY AND SUBMIT CORRECTIVE ACTION PLAN

Alternatively, the Pharmacy may pay the recommended civil monetary penalty within thirty (30) days of the date of this Notice, in the form of a certified check or money order made payable to the Maryland Board of Pharmacy.

Please mail the check or money order to:

Wells Fargo Bank Attn: State of MD – Board of Pharmacy Lockbox 2051 7175 Columbia Gateway Drive Columbia, MD 21046

NOTE: Please include the case number, <u>20-377</u>, on your check or money order to ensure proper assignment to your case.

The Pharmacy shall also submit to the Board a corrective action plan within thirty (30) days of the date of this Notice detailing, at minimum, actions to be taken to remedy the above labeling deficiency and an anticipated date of correction.

Upon the Pharmacy's payment of the civil monetary penalty and submission of a corrective action plan, this Notice will constitute the Board's final action with respect to the inspection dated August 2, 2019, and shall be a public document and order in accordance with the Maryland Public Information Act, Md. Code Ann., General Provisions Art. § 4-101, et seq., and reported and posted in accordance with State and federal laws.

If you have any questions concerning the instructions contained in this letter, please contact Donna Goldberg, R.Ph., J.D., at 410-764-3768.

Sincerely,

Deena Speights-Napata, M.A.

**Executive Director** 

Andrew Militello, Walgreens, Director of Pharmacy & Retail Operations Linda Bethman, Board Counsel